REMARKS

Specification Amendments

Applicant has amended the specification to update the cross-reference to earlier-filed applications from which this application claims priority and benefit as required by the Examiner. This amendment adds no new matter.

Claim Amendments

Applicant has canceled claims 10-24 without prejudice. Applicant has amended claim 1 to recite "a composition comprising a glycoprotein preparation, said glycoprotein having an immunoglobulin CH2 domain said CH2 domain having at least one N-linked oligosaccharide wherein substantially all of the oligosaccharide is a G2 oligosaccharide and wherein the amount of said glycoprotein containing a G1 or G0 oligosaccharide does not exceed 10% by weight of the preparation." Support for this amendment appears, e.g., on page 11, lines 3-31; page 14, lines 9-16; and page 16, lines 8-23.

None of these amendments adds new matter. After entry of the amendments, claims 1-9 and 25-29 will be pending.

Provisional Obviousness Double Patenting Rejection

The Examiner has provisionally rejected claims 1-9 and 25-29 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1, 9, 20, 35, 37, 39, 41 and 43 of copending Application No. 10/744,844.

No action is believed required by applicant at this time as the alleged conflicting claims have not in fact been patented.

The Rejection under 35 U.S.C. § 102

The Examiner has rejected claims 1-5, 25 and 28 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kumpel et al. Hum. Antibod. Hybridomas 5:143-151 (1994) ("Kumpel"). The Examiner contends that Kumpel teaches human monoclonal antibodies wherein substantially all of the oligosaccharide found on said antibody is in the G2 form. The Examiner further states that the antibodies are in a composition form in

a pharmaceutically acceptable carrier (e.g. tissue culture media). Finally, the Examiner notes that antibody 2B6 is an IgG1 antibody and that it is inherently in a container with a label because otherwise it could not be identified. Applicant respectfully traverses.

Kumpel describes a monoclonal antibody designated 2B6 produced from an EBV-transformed B-lymphoblastoid cell line and said to contain 78.7% digalactosyl oligosaccharides, 17.7% monogalactosyl oligosaccharides and 3.6% agalactosyl oligosaccharides (Table 1 and text on page 145). Accordingly, Kumpel describes a composition where 21.3% of the oligosaccharides are said to be either monogalactosyl or agalactosyl. As described above, applicant has amended claim 1 to recite that the amount of said glycoprotein containing a G1 or G0 oligosaccharide does not exceed 10% by weight of the preparation. Further, the amounts of G0, G1, and G2 on the 2B6 antibody were measured after chemical removal of terminal sialic acid residues and Table 1 of Kumpel shows that fully 21.7% of the oligosaccharides 2B6 were sialylated (identified as A1 and A2). In contrast, G0, G1, and G2 according to the present invention have no terminal sialic acid residues (see page 11, lines 27-31 of the specification). Therefore, Kumpel does not describe a composition comprising a glycoprotein where substantially all of the oligosaccharide is a G2 oligosaccharide as recited in the instant claims.

Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(a).

The Rejection under 35 U.S.C. § 103

The Examiner has rejected claims 1-9 and 25-29 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kumpel in view of Maras et al. (US Patent 5,834,251; "Maras") and prior art disclosed in the specification (page 2 and page 19, last paragraph, continued on next page). The Examiner states that Kumpel teaches human monoclonal antibodies wherein substantially all of the oligosaccharide found on said antibody is G2, that said antibodies are in composition form contained in a pharmaceutically acceptable carrier, and that antibody 2B6 in Kumpel is an IgG1 antibody. The Examiner further states that Figure 3 of Kumpel teaches that antibodies with substantially all G2 oligosaccharides have increased lysis of target cells in comparison with the same antibody which is produced in a manner that results in low G2. The Examiner

acknowledges that Kumpel does not teach the molecules of claim 6-9 or articles of manufacture of claim 29. The Examiner further contends that Maras teaches that β-1,4 galactosyltransferase can be used to modify the oligosaccharide profile of a glycoprotein and that Kumpel teaches that this enzyme is involved in the production of G2 oligosaccharides. Finally, the Examiner states that references cited in the instant specification describe antibodies, immunoadhesins and chimeric molecules recited in claims 6-9. Applicant respectfully traverses.

Contrary to the Examiner's contention, Kumpel does not teach increased lysis of target cells using an antibody composition wherein substantially all of the oligosaccharide found on said antibody is G2. In fact, Kumpel does not describe at all the lysis of target cells for an antibody after chemical removal of the sialic acid residues. Thus, Kumpel does not describe at all the lysis properties of an antibody composition wherein substantially all of the oligosaccharide found on said antibody is G2 as recited in the instant claims. At best, Kumpel describes lysis properties of a heterogeneous mixture of different glycoforms with different sialylation levels such as was available in the prior art. Furthermore, Kumpel emphasizes several times that sialylation itself may be an important factor in antibody-mediated lysis (see, e.g., abstract and page 149, right column). Accordingly, Kumpel alone or in combination with Maras fails to provide the motivation to produce applicant's claimed compositions wherein substantially all of the oligosaccharide found on said antibody is G2.

Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

SUMMARY

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is strongly encouraged to call the undersigned at the number indicated below.

In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicant petitions the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicant respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
GENENTECH, INC.

Date: 2/2/07 By: _____

Grant Kalinowski
Reg. No. 48,314
Telephone No. (650) 467-2607